

CAUSE NO. \_\_\_\_\_

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	
	§	
LINDA GONZALEZ d/b/a EL PASO	§	
HEALTH CENTER d/b/a THE CENTER	§	
FOR COLON HYDROTHERAPY d/b/a	§	
LINDA GONZALES AND ASSOCIATES	§	TRAVIS COUNTY, T E X A S
	§	
Defendants.	§	____ JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, plaintiff, acting by and through Attorney General GREG ABBOTT, filing Plaintiff's Original Petition complaining of and against Defendant LINDA GONZALEZ d/b/a EL PASO HEALTH CENTER d/b/a THE CENTER FOR COLON HYDROTHERAPY d/b/a LINDA GONZALEZ AND ASSOCIATES ("herein after Defendant LINDA GONZALEZ" or "Defendant"), and would respectfully show the court the following:

**JURISDICTION**

1. This suit is brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the STATE OF TEXAS and in the public interest under the authority granted to him by §431.047 (b) of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. ("TFDCA") and any regulations promulgated pursuant to this law, upon the grounds that the Commissioner of Health of the State of Texas and his authorized agents find that Defendant LINDA GONZALEZ has violated and is threatening to violate provisions of §431.021 of the TFDCA.

2. This suit is also brought by Attorney General GREG ABBOTT through his Consumer Protection Division in the name of the State of Texas under the authority granted to him by §17.47 of the Texas Deceptive Trade Practices Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.*, (“DTPA”) upon the grounds that Defendant LINDA GONZALEZ has engaged in false, misleading and deceptive acts and practices in the conduct of trade or commerce as defined and declared unlawful by §17.46 (a) and (b) of the DTPA.

### **PARTY DEFENDANT**

3. Defendant LINDA GONZALEZ is an individual doing business in this state as EL PASO HEALTH CENTER d/b/a THE CENTER FOR COLON HYDROTHERAPY d/b/a LINDA GONZALEZ AND ASSOCIATES at 2210-A N. Piedras, El Paso, Texas 79330, and may be served with process by serving her at her home address 2610 Savannah Ave, El Paso, Texas 79930.

### **VENUE**

4. Venue of this action lies in Travis County on the basis of §17.47(b) of the DTPA.

5. Venue of this action lies in Travis County on the basis of §431.047 (c) and §431.0585(d) of the TFDCA.

### **PUBLIC INTEREST**

6. By reason of the institution and operation of the unlawful practices set forth herein, Defendant LINDA GONZALEZ has and will cause immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and will also cause adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

## **TRADE AND COMMERCE**

7. Defendant LINDA GONZALEZ is engaged in trade and commerce, as that term is defined by §17.45(6) of the DTPA, in that she is or was engaged in the business of advertising and/or marketing and delivering colon cleansing services in Texas.

## **NOTICE BEFORE SUIT**

8. Pursuant to §17.47(a) of the Deceptive Trade Practices Act, contact has been made with the Defendant LINDA GONZALEZ herein to inform Defendant LINDA GONZALEZ of the unlawful conduct alleged herein, by letter mailed by certified mail, return receipt requested.

## **ACTS OF AGENTS**

9. Whenever in this petition it is alleged that Defendant LINDA GONZALEZ did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by the officers, agents or employees of said Defendant, and in each instance, the officers, agents or employees of said Defendant that were then authorized to and did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of the Defendant.

## **OVERVIEW OF NATURE OF DEFENDANT'S OPERATION**

10. Defendant LINDA GONZALEZ advertises, markets, and provides colon cleansing services using three colon irrigation devices and rectal nozzles in Texas. Defendant LINDA GONZALEZ advertised and solicited customers to provide colon cleansing for constipation, other bowel problems, and/or general well-being in the El Paso, Texas area, as shown below.

11. Defendant LINDA GONZALEZ is not a licensed practitioner as defined by 25

T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act.

12. Defendant LINDA GONZALEZ purchased and received in commerce three prescription colon irrigation systems and thousands of prescription rectal nozzles without authorization from a licensed practitioner to purchase or possess them as required by state and federal law, and, therefore, misbranded them.

13. Defendant LINDA GONZALEZ used these prescription colon irrigation devices to provide colon cleansing to hundreds of patients in El Paso, Texas without a licensed practitioner ordering a procedure on a patient and without a licensed practitioner supervising her use of the prescription medical devices. This use without practitioner involvement, as required by state and federal law, misbranded Defendant's devices.

14. Defendant LINDA GONZALEZ used these prescription medical devices for other purposes than the approved intended use of colon cleansing when medically indicated as shown below. Defendant's use of these prescription medical devices for colon cleansing for general well being, a use that has not been approved by the FDA as safe and effective, adulterated these devices.

15. Defendant LINDA GONZALEZ continued to perform colon cleansing without practitioner involvement even after she had been informed by the Texas Department of Health ("TDH"), on December 17, 2002, that the colon irrigation devices that were in her possession were prescription medical devices and could only be purchased and/or possessed, used upon the order of, and the use supervised by a practitioner.

16. Defendant LINDA GONZALEZ advertises under the category of "Colonic Irrigation" in the SBC El Paso Smart Yellow Pages 2003 under the names, The Center for Colon Hydrotherapy and Linda Gonzalez and Associates. In this advertisement, Defendant LINDA

GONZALEZ promotes colonic irrigation to “re-energize for life” which is not the use for which these prescription colon irrigation devices have been approved by FDA. Defendant LINDA GONZALEZ misbrands her prescription medical devices under state and federal law by advertising them for a use other than the FDA approved use.

17. Defendant LINDA GONZALEZ fails to disclose in her advertisement in the SBC El Paso Smart Yellow Pages 2003 that colonic irrigation requires an order from a practitioner licensed in Texas to use or order the use of prescription medical devices.

18. Defendant LINDA GONZALEZ also advertises and promotes colon hydrotherapy by displaying and providing brochures to patients without disclosing that the “FDA-registered equipment” that she uses is considered by FDA to be a prescription medical device and that an order from a practitioner licensed in Texas was required for each procedure.

19. Defendant LINDA GONZALEZ also advertises and promotes colon hydrotherapy by displaying and providing brochures to patients that contains a section titled, Historical View, that makes a general well-being claim by stating “It was an acceptable practice in Parisian society to enjoy as many as three or four enemas a day, the belief being that an internal washing or "lavement" was essential to well-being.” Defendant falsely advertised and misbranded her colon irrigation devices by advertising the use of these devices for an unapproved use.

20. Defendant LINDA GONZALEZ also advertises and promotes colon hydrotherapy by displaying and providing brochures to patients that contains a section titled, How Many Colon Hydrotherapy Sessions Does One Need? that makes a general well-being claim by stating “Just as some people exercise on a daily or weekly basis to tone and tighten their outer body, some people follow an ongoing cleansing, toning, and rebuilding regime for the inner body. Colon hydrotherapy could be used as part of any regular maintenance program.” Defendant

falsely advertised and misbranded her colon irrigation devices by advertising the use of these devices for an unapproved use.

Inspection of December 17, 2002:

21. On December 17, 2002, an investigator from the Texas Department of Health (“TDH”) inspected Defendant LINDA GONZALEZ as a result of obtaining Defendant’s name as a colon cleansing clinic that was participating in a study, not approved by FDA, to reclassify colon irrigation systems for general well being.

22. TDH determined that Defendant LINDA GONZALEZ purchased and received in commerce two Jimmy John III colon irrigation devices from Colon Therapeutics, Inc., one Hydro-San colon irrigation device from Specialty Health Product, and rectal nozzles designed to be used with each of these colon irrigation systems and that all of these devices are considered by FDA to be prescription devices.

23. TDH determined that Defendant LINDA GONZALEZ did not have a licensed practitioner to authorize her purchase or possession of the three colon irrigation systems or the rectal nozzles.

24. TDH also determined that Defendant LINDA GONZALEZ did not have a licensed practitioner ordering the colon cleansing procedures for patients or supervising Defendant LINDA GONZALEZ’s use of the prescription medical devices to perform colon cleansing for any purpose.

25. TDH also determined that Defendant LINDA GONZALEZ performed colon cleansing for a variety of reasons, such as constipation and other bowel problems, as well as for general well-being.

26. TDH conducted a random review of ten client records kept by Defendant LINDA

GONZALEZ and found that none of these files contained any order for a colonic irrigation from a physician and that all of these patients had colon irrigations provided by Defendant LINDA GONZALEZ. Records for hundreds of other patients were not reviewed at this time.

27. TDH issued a “Notice of Detention” on December 17, 2002, notifying Defendant LINDA GONZALEZ that the Texas Department of Health had detained Defendant’s three colon irrigation systems, 242 Jimmy John III rectal nozzles, and 69 Hydro-Kit Grande rectal nozzle kits after determining that these devices were adulterated, misbranded, and/or violated additional provisions of the TFDCA.

28. In addition, Defendant LINDA GONZALEZ was notified verbally during the inspection by TDH that she was not allowed to move, sell, or use the detained devices without permission of TDH. The Notice of Detention form cited to Section 431.021(j) of the Texas Health and Safety Code as declaring that the use, removal, or disposal of a detained article from the premises by sale or otherwise without written permission from the Commissioner of Health, an authorized agent, or the court to be an unlawful and prohibited act.

Inspection of May 5-8, 2003:

29. On May 5-8, 2003, an inspection was conducted by the TDH of Defendant LINDA GONZALEZ at her El Paso office. The investigator confirmed that Defendant LINDA GONZALEZ had continued to conduct colon cleansing procedures using prescription medical devices without orders for the procedure from a licensed practitioner despite notification that this was unlawful on December 17, 2002.

30. Defendant LINDA GONZALEZ performed at least 590 colon irrigations without orders from a licensed practitioner from January, 2003 through the date of this inspection. TDH again placed detention tags on Defendant’s three colon irrigation systems and the rectal nozzles

during this inspection notifying Defendant that the previous detention was still in effect based upon the determination that these devices were adulterated, misbranded, and/or violated additional provisions of the TFDCA

Inspection of September 8-11, 2003:

31. On September 8-11, 2003, the TDH attempted to conduct an inspection of Defendant LINDA GONZALEZ to determine that the prescription medical devices which had been detained previously remained in the same place and were not being used in violation of state law.

32. Defendant LINDA GONZALEZ refused to allow TDH to enter the building alleging that she was no longer in business. TDH then issued a finding of violation by Defendant for refusing to allow inspection of detained prescription medical devices.

**OVERVIEW OF REGULATION OF PRESCRIPTION MEDICAL DEVICES**

33. The Texas Food, Drug, and Cosmetic Act lists acts and the causing of acts that are unlawful and prohibited, including, but not limited to, misbranding medical devices in commerce, adulterating medical devices in commerce, and the dissemination of any false advertisement. TDH determines if the use of a medical device violates any prohibited acts depending on the classification and regulation of each medical device by the Federal Food and Drug Administration (“FDA”).

***FDA Regulates and Classifies Medical Devices According to Intended Use***

34. FDA regulates and classifies medical devices for use in humans according to their intended use, relying upon the manufacturer or distributor’s labeling of the device to determine its intended use. FDA is responsible for classifying and approving medical devices after they determine whether they are safe and effective for their stated intended uses.



35. FDA has classified colon irrigation systems intended for “colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations” as Class II medical devices when used for this purpose in 21 C.F.R. §876.5220 (b)(1). Colon irrigation devices are described as usually consisting of a container for fluid; the tubing; the nozzle; a system which enables the pressure, temperature, or flow of water through the nozzle to be controlled; a console-type toilet and necessary fittings to allow the device to be connected to water and sewer pipes; and electrical power to heat the water.

36. FDA approved the colon irrigation devices used by Defendant LINDA GONZALEZ, the Jimmy John III colon irrigation system, the Hydro-San colon irrigation system, the Hydro-Kit Grande Rectal Nozzle, and the Jimmy John Rectal Nozzle, as “substantially equivalent” to other pre-existing colon irrigation devices used for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations based on premarket notification submissions to the FDA pursuant to § 510(k) of the FDCA, 21 U.S.C. § 360(k). Therefore, these devices are Class II medical devices by regulation for this purpose and can only be used for the approved intended use for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations.

37. FDA has also classified colon irrigation systems for other uses than the intended use authorized in 21 C.F.R. §876.5220 (b)(1). FDA classified these colon irrigation systems as class III medical devices when the intended use is for “other uses, including colon cleansing routinely for general well being” as shown in 21 C.F.R. §876.5220 (b)(2).

38. FDA’s classification of colon irrigation systems as Class III medical devices requires that any colonic irrigation system to be used for purposes other than those approved in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being shall have

an approved premarket approval (“PMA”) in effect before being placed in commercial distribution to show that the device is safe and effective for the new intended use . (21 C.F.R. §876.5220 (c)).

39. FDA requires that, unless specifically exempted, a medical device must have “adequate directions for use” as defined in 21 C.F.R. § 801.5 to mean directions under which the layperson can use a device safely and for the purposes for which it is intended. Unless subject to an exemption, a medical device must have “adequate directions for use” or it cannot be sold to or used by a lay person.

***FDA Considers All Colon Irrigation Devices To Be Prescription Medical Devices***

40. FDA defines a prescription device in 21 C.F.R. § 801.109 to be a device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared.

41. The FDA regulations create an exemption from the requirement of having “adequate directions for use” for prescription medical devices in 21 C.F.R. § 801.109. To qualify for an exemption from “adequate directions for use”, a medical device must be in the possession of a practitioner licensed by state law to use or order the use of such device; sold only to or on the prescription or other order of such practitioner for use in professional practice; and the label has to bear the statement “Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_, to be filled in with the descriptive designation of any practitioner licensed by state law in which he practices to use or order the use of the device.

42. The FDA considers the colon irrigation devices possessed and used by Defendant LINDA GONZALEZ to be prescription medical devices, as defined in 21 C.F.R.

§ 801.109, and these devices must comply with all the requirements as cited in paragraph 41 above in order to be exempted from “adequate directions for use”. Because the colon irrigation devices used by Defendant LINDA GONZALEZ are prescription devices, these devices cannot bear adequate directions for safe use by a layperson, and therefore must comply with the exemption requirements in paragraph 41.

43. State law incorporates a definition of prescription devices in 25 T.A.C. §229.433 (23) as a “restricted device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which adequate directions for use cannot be prepared”.

44. In addition, prescription medical devices are restricted devices because they are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Restricted devices pursuant to 25 T.A.C. §229.433 (27) are devices that are subject to certain controls related to sale, distribution, or use as specified in §520(e)(1) of the Federal Food, Drug and Cosmetic Act. Because Defendant LINDA GONZALEZ’s colon irrigation devices are prescription medical devices, under Texas law her devices are also restricted devices since they are subject to certain controls related to the sale, distribution, or use, as defined in 25 T.A.C. §229.433 (27).

45. Prescription colon irrigation devices are “dangerous drugs” pursuant to §483.001 (2) of the Texas Dangerous Drug Act because these devices bear or are required to bear a legend to comply with federal law regarding their sale as prescription medical devices pursuant to 21 C.F.R. § 801.109.

46. Under Texas law, only those practitioners listed in § 483.001(12) of the Texas Dangerous Drugs Act, also defined in 25 T.A.C. §229.433 (22), are authorized to purchase,

possess, use or order the use of prescription or restricted medical devices, including prescription colon irrigation devices. The only practitioners licensed in Texas who can purchase, possess, use or order the use of colon irrigation devices on humans in the course of their professional practice are those practitioners licensed by the Texas Board of Medical Examiners.

47. Defendant LINDA GONZALEZ is not a practitioner as defined by 25 T.A.C. §229.433 (22) or §483.001(12) of Texas Dangerous Drug Act and therefore colon irrigation devices in her possession and use are not exempted from having adequate directions for use.

#### **DEFENDANT’S DEVICES ARE MISBRANDED**

48. As set out in paragraphs 1 through 47 and incorporated herein, Section 431.112(f)(1) of the TFDCa provides that a device is misbranded unless its labeling bears adequate directions for use or unless the device has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services. Since the prescription colon irrigation devices used by Defendant LINDA GONZALEZ cannot bear instructions for safe use by a layperson and only are exempt from this requirement pursuant to 21 C.F.R. § 801.109, Defendant LINDA GONZALEZ is required to have a licensed practitioner to purchase and possess, to order the procedure, and to supervise the use of colon irrigation devices.

49. Defendant LINDA GONZALEZ is not a licensed practitioner as defined by §483.001(12) of The Dangerous Drug Act nor did she have a licensed practitioner authorizing her purchase and possession, ordering colon cleansing procedures for patients, or supervising the colon cleansing procedures.

50. Defendant LINDA GONZALEZ’s purchase and possession of prescription colon irrigation devices; lack of written orders for colon cleansing procedures for each patient; and the use of colon irrigation systems without authorization and supervision of a practitioner/physician

licensed in Texas misbrand these device pursuant to § 431.112 (f) of the TFDCA.

51. Subsequently, Defendant LINDA GONZALEZ performed colon cleansing without authorization from a practitioner licensed in Texas to purchase, possess, or use prescription colon irrigation devices which are also restricted devices, as defined in by 25 T.A.C. §229.433 (27), since they are subject to certain controls related to the sale, distribution, or use. Therefore, Defendant LINDA GONZALEZ's purchase, possession, and use of colon irrigation devices as restricted devices without authorization, a written order for colon cleansing procedures, and supervision by a practitioner licensed in Texas also misbrand these device pursuant to § 431.112 (r) of the TFDCA.

52. Under the terms of § 431.021(b) of the TFDCA, the misbranding of any device in commerce in Texas is unlawful and prohibited. Defendant LINDA GONZALEZ's purchase, possession, and use of prescription and restricted medical devices without authorization and supervision by a practitioner licensed in Texas misbrand these devices in Texas.

53. Each colon cleansing that Defendant LINDA GONZALEZ has performed in Texas without an order from a licensed practitioner or without supervision by practitioner licensed in Texas violates Texas law and is prohibited and unlawful because this use without such an order or supervision from a licensed practitioner misbrands the colon irrigation devices.

#### **DEFENDANT'S DEVICES ARE ADULTERATED**

54. As set out in paragraphs 1 through 53 and incorporated herein, colon irrigation devices used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including general well being purposes, have not been approved previously by FDA and are, therefore, not preamendment devices and are by regulation (21 C.F.R. §876.5220 (b)(2)) and by statute classified as Class III medical devices and may not be marketed without an approved application for Premarket Approval ("PMA") under section 515 of the Federal Food, Drug, and Cosmetic Act.

FDA has not approved any application for PMA for colon irrigation devices for any purposes, including general well being.

55. The prescription colon irrigation devices used by Defendant LINDA GONZALEZ are Class III medical devices when used for purposes other than those stated in 21 C.F.R. §876.5220 (b)(1), including colon cleansing routinely for general well being, and require premarket approval, or must fall into an exemption from such approval, before they can be used in the marketplace. FDA must review each Class III medical device to determine if it is safe and effective for its use(s) before the device can be introduced into commerce.

56. Defendant LINDA GONZALEZ's colon irrigation devices are Class III medical devices when used for other uses (than those stated in 21 C.F.R. §876.5220 (b)(1)), including general well being, and were required to receive premarket approval from FDA, but are used in commerce even though they did not receive such approval. (21 U.S.C.A. §351(f) (1)(A), section 501(f)(1)(A) of the FFDCA). A device is adulterated if it is a Class III medical device, whether by statute or regulation, and is in the marketplace without receiving approval from FDA.

57. Defendant LINDA GONZALEZ's devices are adulterated under state law, according to §431.111(f)(1)(A) of the TFDCA. Section 431.111 states that a device shall be deemed to be adulterated :

(f)(1) if it is a class III device:

(A)(i) that is required by a regulation adopted under Section 515(b) of the federal Act to have an approval under that section of an application for premarket approval and that is not exempt from Section 515 as provided by Section 520(g) of the federal Act; and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the United States Food and Drug Administration by the 90th day after the date of adoption of the regulation; or  
(II) for which that application was filed and approval was denied or withdrawn, for which that notice was filed and was declared incomplete, or for which approval of the device under the protocol was withdrawn.

58. Under the terms of § 431.021(b) of the TFDCA, the adulteration of any device in commerce in Texas is unlawful and prohibited. Defendant LINDA GONZALEZ violates § 431.021(b) of the TFDCA and adulterates her prescription colon irrigation devices with each use that FDA codifies as a Class III medical device use, including general well being, since these devices have not been approved through pre-market approval as required by FDA to show their safety and effectiveness for Class III uses.

**DEFENDANT’S ADVERTISEMENTS ARE FALSE, MISLEADING OR DECEPTIVE**

59. As set out in paragraphs 1 through 58 and incorporated herein by reference, Defendant LINDA GONZALEZ represented that her prescription colon irrigation devices have uses other than those for which FDA has allowed the devices to be sold or used, including for general well being. Defendant’s representations for the use of prescription colon irrigation devices for unapproved uses constitute false advertisements in violation of § 431.021(f) of the TFDCA.

60. Defendant LINDA GONZALEZ also has violated § 431.021(f) of the TFDCA because Defendant’s representations of the illegal use of her medical devices constituted false advertisements under the TFDCA because she solicited persons to purchase services which violated § 431.021(b) of the TFDCA.

61. Defendant LINDA GONZALEZ advertised and promoted the unapproved use of prescription colon irrigation devices to the public although these devices are not intended for self-medication or for use without practitioner supervision and ordering without disclosing that these acts are unlawful and prohibited by the TFDCA.

62. Such representations listed above constitute advertising within the definition set out in §431.002(1) of the TFDCA since they are intended to induce consumers to purchase Defendant LINDA GONZALEZ’s services through her unapproved uses of prescription colon

irrigation devices without involvement of a practitioner licensed in Texas.

63. Any such advertisement by Defendant LINDA GONZALEZ of a prescription medical device directed toward the public without disclosing that a licensed practitioner must order the colon cleansing procedure to be administered with prescription colon irrigation devices and for unapproved uses are declared to be false by the terms of §431.182(a) of the TFDCA.

### **PROHIBITED ACTS**

64. Defendant LINDA GONZALEZ, as set out in paragraphs 1 through 63 and incorporated herein by reference, have committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA with each colon cleansing performed using prescription medical devices without an order or supervision by a licensed practitioner:

- a. Introducing and delivery into commerce a misbranded or adulterated prescription colon irrigation device with each use of Defendant's prescription colon irrigation devices, in violation of §431.021(a);
- b. Misbranding of a prescription colon irrigation device in commerce, in violation of §431.021(b);
- c. Adulteration of a prescription colon irrigation device in commerce, in violation of §431.021(b)
- d. Receiving in commerce a prescription colon irrigation device that is adulterated or misbranded, in violation of §431.021(c);
- e. Disseminating false advertising, in violation of §431.021(f);
- f. Removing or using a detained article, in violation of §431.021(j); and
- g. Failing to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act, in violation of §431.021(t)(1)(B).

### **VIOLATIONS OF THE DTPA**

65. Defendant LINDA GONZALEZ, as set out in paragraphs 1 through 64 and



incorporated herein by reference, in the course and conduct of trade and commerce, have directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

- a. Causing confusion as to the approval of a good by using prescription colon irrigation devices without the authorization or supervision of a practitioner licensed in Texas;
- b. Failing to disclose that prescription colon irrigation devices are only to be sold under the order of a practitioner licensed in Texas and Defendant's possession of the devices violate state law;
- c. Failing to disclose that prescription colon irrigation devices are only to be used under the supervision of a practitioner licensed in Texas and Defendant does not have the required supervision;
- d. Failing to disclose that colon cleansing using prescription colon irrigation devices can only be performed upon the order of a licensed practitioner in Texas;
- e. Falsely advertising to a consumer that colon cleansing services using prescription colon irrigation devices for unapproved purposes were legal services which were available for purchase;
- f. Falsely representing to a consumer that colon cleansing using prescription colon irrigation devices can legally be performed without the supervision or order of a practitioner licensed in Texas;
- g. Failing to disclose that federal and state law prohibit colon cleansing using prescription colon irrigation devices for general well-being because this use has not been proven to be safe and effective to FDA;
- h. Falsely advertising that colon cleansing using prescription colon irrigation devices is available to the general public when it is not; and
- i. Failing to disclose that Defendant's prescription colon irrigation devices are approved for colon cleansing, when medically indicated, such as before radiologic or endoscopic examinations only.

66. Moreover, the Consumer Protection Division has reason to believe that the above actions specifically violate §17.46 (a) and the following provisions of §17.46 of the DTPA:

- (b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;
- (b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
- (b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

### **INJURY TO CONSUMERS**

67. By means of the foregoing unlawful acts and practices which were producing causes of injury to the persons affected, Defendant has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

### **CONTINUING VIOLATIONS**

68. By reason of the institution and continued operation of the acts and practices described in paragraphs 1 through 67 above, Defendant LINDA GONZALEZ has violated and will continue to violate the laws as hereinabove alleged. Defendant LINDA GONZALEZ, unless restrained by this Honorable Court, will continue violating the laws of the State of Texas and injury, loss and damage will result to the State of Texas and to the general public. Defendant LINDA GONZALEZ has violated and continue to violate these sections of the TFDCA and the DTPA.

### **PRAYER**

69. WHEREFORE, PREMISES CONSIDERED, Plaintiff prays that Defendant LINDA GONZALEZ be cited according to law to appear and answer herein; that after due notice and hearing a TEMPORARY INJUNCTION be issued and upon final hearing a PERMANENT

INJUNCTION be issued restraining and enjoining Defendant individually and by their agents, servants, employees, and representatives from making the representations, doing the acts, and engaging in the practices set out in the preceding paragraphs as well as from making the following representations and doing the following acts and engaging in the following practices in the pursuit and conduct of trade or commerce within the State of Texas as follows:

- a. Introducing and delivering into commerce misbranded or adulterated prescription colon irrigation devices, including rectal nozzles;
- b. Misbranding or adulteration of prescription colon irrigation devices, including rectal nozzles in commerce;
- c. Receiving in commerce prescription colon irrigation devices, including rectal nozzles that are adulterated or misbranded;
- d. Disseminating false advertising about prescription colon irrigation devices, including rectal nozzles;
- e. Removing or using detained prescription colon irrigation devices, including rectal nozzles;
- f. Purchasing and possessing prescription colon irrigation devices, including rectal nozzles, without a practitioner licensed under Texas law to purchase and possess such devices;
- g. Using prescription colon irrigation devices, including rectal nozzles, without the supervision of a practitioner licensed by Texas law to use such devices;
- h. Using prescription colon irrigation devices, including rectal nozzles, without a written order for each use from a practitioner licensed under Texas law to order the use of such prescription devices;
- i. Using prescription colon irrigation devices, including rectal nozzles for treating diseases of the body or for uses, including general well being for which FDA has not approved these devices;
- j. Failing to comply with federal medical device reporting requirements, as required by 21 CFR § 803 and Section 519 of the federal Act;
- k. Falsely advertising or falsely representing that prescription colon irrigation devices, including rectal nozzles, can be self-administered;

- l. Falsely advertising or falsely representing that prescription colon irrigation devices, including rectal nozzles, are effective for treating diseases of the body for which FDA has not approved these devices;
- m. Falsely advertising or falsely representing that prescription colon irrigation devices, including rectal nozzles, are effective for uses, including general well being, for which FDA has not approved these devices;
- n. Failing to provide a notice required by Section 510 (k) of the Federal Act or file an application for premarket approval as required by Section 515 of the Federal Act prior to introducing into commerce a prescription colon irrigation device, including a rectal nozzle, for a new or unapproved use;
- o. Failing to comply with any requirement prescribed under Section 520(g) of the Federal Act and furnishing any notification or information required by or under Section 519 or 520(g) of the Federal Act;
- p. Causing confusion as to the approval of a good by allowing consumers to use prescription colon irrigation devices, including rectal nozzles, for self-use;
- q. Failing to disclose that the prescription devices used for colon irrigation are only to be used under the written order and supervision of a practitioner licensed in Texas;
- r. Using prescription colon irrigation devices, including rectal nozzles, that have been detained by the Texas Department of Health unless the detention has been released; and
- s. Failing to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

70. Plaintiff further prays that upon final hearing that this Court order Defendant LINDA GONZALEZ, within 30 days of the order signed by the Court, at her own expense to destroy all devices pursuant to § 431.050 of the TFDCA, currently detained by TDH, unless said devices are brought into compliance with Chapter 431 and have been released from detention by TDH based upon Defendant's assurance that the devices will be used in a manner consistent with the law and the terms of this injunction or transferred or sold to a licensed practitioner for the practitioner's use in his/her own practice.

71. Plaintiff further prays that upon final hearing this Court order Defendant LINDA GONZALEZ to pay civil penalties to the State of Texas up to \$25,000 per violation per day for

each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

72. Plaintiff further prays that upon final hearing that this court order Defendant LINDA GONZALEZ to pay to the State of Texas and to the TEXAS COMMISSIONER OF HEALTH their reasonable expenses incurred in obtaining injunctive relief under §431.047 of the TFDCA, including investigative costs, court costs, reasonable attorneys' fees pursuant to § 431.047(d) of the TFDCA.

73. Plaintiff further prays that upon final hearing this Court order Defendant LINDA GONZALEZ to restore all money or other property taken from identifiable persons by means of Defendant LINDA GONZALEZ's unlawful acts or practices, or, in the alternative, award judgment for damages to compensate identifiable persons for such losses as provided in §17.47(d) of the DTPA.

74. Plaintiff further prays, that upon final hearing, this Court order Defendant LINDA GONZALEZ to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

75. Plaintiff further prays that upon final hearing this Court order Defendant LINDA GONZALEZ to pay an additional amount in civil penalties, not to exceed a total of \$250,000.00, to the State of Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

76. Plaintiff further prays that upon final hearing that this Court order Defendant LINDA GONZALEZ to pay to the STATE OF TEXAS attorney fees and to pay the costs of court pursuant to the TEX. GOVT. CODE §402.006(c).

77. Plaintiff further prays that the court set this matter for trial and upon final hearing issue a permanent injunction against Defendant LINDA GONZALEZ.

78. Plaintiff further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

**Plaintiff State of Texas**

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